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Attorney for Defendant ELIZABETH A. HOLMES

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. ELIZABETH HOLMES and RAMESH "SUNNY" BALWANI, Defendants.	Case No. CR-18-00258-EJD **DECLARATION OF JOHN D. CLINE IN SUPPORT OF MOTION TO COMPEL**

1. My name is John D. Cline. I am one of the attorneys for defendant Elizabeth Holmes. I submit this declaration in support of Ms. Holmes' Motion to Compel Compliance With Subpoena Duces Tecum to Roger Parloff.

2. Attached as Exhibit A is a true and correct copy of a subpoena duces tecum that I sent to Mr. Parloff by email on August 24, 2021, together with the cover letter that accompanied the subpoena.

3. Attached as Exhibit B is a true and correct copy of objections to the subpoena duces tecum that I received by email from Mr. Parloff's attorney on September 15, 2021.

4. Attached as Exhibit C is a true and correct copy of government trial exhibit 1749. The exhibit consists of an article Mr. Parloff wrote for the June 2014 issue of Fortune magazine.

5. Attached as Exhibit D is a true and correct copy of government trial exhibit 1750. The exhibit consists of the cover of the Fortune issue in which Mr. Parloff's June 2014 article appeared.

6. Attached as Exhibit E is a true and correct copy of government trial exhibit 3033. The exhibit consists of an article Mr. Parloff published in Fortune in January 2016.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 17th day of September 2021.

/s/ John D. Cline
JOHN D. CLINE

EXHIBIT A

CAND 89A (Rev. 6/17) Subpoena to Testify in a Criminal Case

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA,

Plaintiff,

v.

Elizabeth Holmes

Defendant(s).

SUBPOENA TO TESTIFY
IN A CRIMINAL CASE

Case No.: CR 18-00258-01-EJD

TO: Roger Parloff

YOU ARE COMMANDED to appear at the place, date, and time specified below, or any subsequent date and time set by the court, to testify in the above-referenced case. This subpoena shall remain in effect until you are granted leave to depart by the court or by an officer acting on behalf of the court.

PLACE				COURTROOM/JUDGE
☐ U.S. Courthouse 450 Golden Gate Ave. San Francisco, CA 94102	☑ U.S. Courthouse 280 South First St. San Jose, CA 95113	☐ U.S. Courthouse 3140 Boeing Ave. McKinleyville, CA 95519	☐ U.S. Courthouse 1301 Clay Street Oakland, CA 94612	Ctr. 4 / Davila, J. DATE AND TIME 9/7/2021 9:00 am

☒ You are also commanded to bring with you the following document(s) or object(s):

See Addendum

NOTE: Subpoena forms for the production of documents or objects at or in advance of the trial, hearing or proceeding at which the items are to be offered in evidence (CAND 89B, *Subpoena to Produce Documents or Objects in a Criminal Case)* or for the production of state law enforcement personnel or complaint records (CAND 89C, *Subpoena to Produce State Law Enforcement Personnel Or Complaint Records in a Criminal Case*) are available at the Court's website: cand.uscourts.gov.

~~U.S. MAGISTRATE JUDGE OR~~ CLERK OF COURT	DATE
Susan Y. Soong	3/26/2021
(By) Deputy Clerk: Cita F. Escalano	

ATTORNEY'S NAME, ADDRESS AND PHONE NUMBER

Patrick J. Looby
Williams & Connolly LLP
725 Twelfth Street NW Washington, DC 20005
plooby@wc.com (202) 434-5150

PROOF OF SERVICE		
RECEIVED BY SERVER	DATE	PLACE
SERVED	DATE	PLACE
SERVED ON (PRINT NAME)		FEES AND MILEAGE TENDERED TO WITNESS ☐ YES ☐ NO AMOUNT $
SERVED BY (PRINT NAME)		TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
SIGNATURE OF SERVER

ADDRESS:

ADDITIONAL INFORMATION

Addendum

Please bring with you the following documents:

(1) The notes and audio recordings of your March 31, 2014 meeting with David Boies regarding Theranos.

(2) The notes and audio recordings of your 2014 call with Greg Wasson regarding Theranos.

(3) The notes and audio recordings of your April 17, 2014 meeting with Dr. David Helfet regarding Theranos.

(4) The notes and audio recordings of your 2014 call with Mark Laret regarding Theranos.

(5) The notes and audio recordings of your April 17, 2014 call with Bill Perry regarding Theranos.

(6) The notes and audio recordings of your June 6, 2014 call with Bert Zimmerli regarding Theranos.

(7) The notes and audio recordings of your May 5, 2015 call with Heather King regarding Theranos.

(8) The notes and audio recordings of your October 30, 2015 call with David Boies regarding Theranos.

(9) The notes and audio recordings of calls or meetings in 2014-2015 with clinical laboratory companies other than Theranos, including but not limited to Quest Diagnostics and Laboratory Corporation of America, made in the course of your reporting on Theranos.

(10) The communications and documents reflecting communications in 2014-2015 with clinical laboratory companies other than Theranos, including but not limited to Quest Diagnostics and Laboratory Corporation of America, made in the course of your reporting on Theranos.

(11) The communications and documents reflecting communications in 2014-2016 with Dawn Schneider regarding Theranos.

(12) The communications and documents reflecting communications in 2014-2016 with David Boies regarding Theranos.

LAW OFFICE OF JOHN D. CLINE

August 24, 2021

VIA EMAIL
Mr. Roger Parloff
[redacted]

Re: *United States v. Elizabeth Holmes*, No. CR 18-00258-EJD--trial subpoena

Dear Mr. Parloff:

I am one of the attorneys representing Elizabeth Holmes. I am enclosing a subpoena requiring your attendance as a witness in Ms. Holmes' upcoming trial. Please let me know whether you will accept service of this subpoena via email, or if you would prefer that we proceed with formal process. Please also advise whether you have retained counsel in relation to this matter. We are prepared to provide a check for the first day's witness fee and mileage allowance.

The trial is set to begin on August 31, 2021, and it is expected to last about three months. The government has listed you as a possible trial witness in its case-in-chief. If you testify as part of the government's case-in-chief, we will attempt to avoid having to recall you in any defense case. If we call you in the defense case, we expect to be able to notify you 48 hours in advance of the time you will be required to appear. You do not have to appear on the date stated on the subpoena--September 7, 2021--if you will provide us with your contact information and agree to appear on 48 hours notice. Also, if you will advise us of any professional or personal commitments during the trial, we will do our best to accommodate them. Please note that we have limited control over the schedule.

The addendum to your subpoena lists documents that you are required to bring with you when you appear to testify. Please contact me with any questions you may have regarding these documents.

Very truly yours,

John Cline

John D. Cline

Enclosure

Office: 415.662.2260 | Cell: 415.302.2401 | Fax: 415.662.2263
cline@johndclinelaw.com | 50 California Street, Suite 1500, San Francisco, CA 94111

EXHIBIT B

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, -against- ELIZABETH HOLMES, Defendant.	Case No. 18-cv-00258-01 EJD **OBJECTIONS OF ROGER PARLOFF TO SUBPOENA**

To: John D. Cline, Esq.
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San Francisco, CA 94111
415-662-2260
cline@johndclinelaw.com

Patrick J. Looby, Esq.
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725 Twelfth Street NW
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Attorneys for Defendant Elizabeth Holmes

Roger Parloff, a nonparty to this action, by his attorneys, **Miller Korzenik Sommers Rayman LLP,** objects to the Subpoena addressed to him dated March 26, 2021 pursuant Federal Rule of Criminal Procedure 17(c)(2) on the grounds set forth below. (The Subpoena was first sent to Mr. Parloff by email on August 24, 2021 while he was in Europe. It has not as yet been served.)

Stipulated Procedure: Mr. Parloff will accept service of the Subpoena as of the date of these Objections on the following conditions:

1) Counsel for Defendant and counsel for Mr. Parloff have agreed to a briefing procedure by which Mr. Parloff may Move To Quash or Modify the Subpoena under Rule 17(c)(2).
2) Mr. Parloff will be asserting the Reporter's Privilege as one of several grounds for his Objections to the Subpoena. Instead of filing a motion on general terms citing that Privilege, Mr. Parloff will initiate the Rule 17(c)(2) process by serving Defendant's counsel with his objections to the Subpoena. Counsel may then meet and confer promptly so that Defendant's counsel can file a Motion To Compel as to matters that could not otherwise be resolved or narrowed.
3) When the Motion To Compel is filed and served on Mr. Parloff's counsel, Mr. Parloff will have two weeks in which to serve and file a Cross-Motion to Quash and/or Opposition under Rule 17(c)(2). The parties may file opposition or reply papers, or not, as they deem appropriate.
4) As to any oral argument or other proceedings on the anticipated motions concerning the Subpoena, Counsel for Defendant and Counsel for Mr. Parloff consent to and have no objection to each other's remote appearance for such proceedings.

Objections: In response to the Subpoena which seeks trial testimony and documents (Document Requests 1 -12 annexed to the Subpoena), Mr. Parloff asserts the following objections as grounds for quashing or otherwise limiting the Subpoena both as to documents and testimony sought:

a) ***Reporter's Privilege***: The records sought are unpublished editorial and reportorial work-product and, therefore, are protected by the Reporter's Privilege. The production of such editorial materials would be an undue imposition upon the freedom of the press under the First Amendment of the U.S. Constitution, Article 8 of the Constitution of the State of New York, the statutory and common law of New York (see, e.g., N.Y. Civ. Rights Law § 79–h), and/or any other applicable state law or rule of evidence protecting journalist newsgathering information and activities, including the Constitution of the State of California Article 1, Section 2, subdivision (b) which expressly provides a reporter's privilege and matches the California Reporter's Privilege Statute, California Evidence Code § 1070. In the Second Circuit, the recognized authority as to the Federal reporter's privilege is set forth in *Gonzales v National Broadcasting Co. Inc.*, 194 F. 3d 29 (2d Cir. 1999). In the Ninth Circuit a similar Reporter's Privilege is recognized in *Schoen v. Schoen*, 5 F.3d 1289 (9th Cir. 1993). The Reporter's Privilege receives analogous deference from the Department of Justice Guidelines, 28 C.F.R. § 50.10.

New York law is applicable because the work that Mr. Parloff did in connection with this *Fortune* feature article about Theranos and any other reporting that he undertook on the subject was largely done in New York at *Fortune* offices and under *Fortune's* editorial structure in New York. Any need for the information Subpoenaed, even if articulated with the required particularized need, is outweighed by the public interest in protecting the editorial work product and confidential information and sources of journalists and the news media. Additionally, the requests lack the particularity and clarity that would permit Defendant Holmes to meet the requisite *particularized need* that, among other things, must be shown in order to overcome the Reporter's Privilege. The blanket Document Requests 1-12 are so expansive and lacking in particularity that they are designed to allow Defendant to "sift" through Mr. Parloff's files in search of documents and statements unknown to

Defendant that *might theoretically and only speculatively* be of some as yet *undefined* interest to her.

Confidential Interviews: Some of the interview notes and recordings sought by the Subpoena and any testimony that might pertain to them are confidential: They were obtained on condition that the interviewees would be kept confidential by Mr. Parloff. Such materials deserve the highest level of protection under the Reporter's Privilege and Mr. Parloff must and will honor those commitments of confidentiality to those sources.

The Limited and Focused Materials Provided: Mr. Parloff has already provided to the prosecution and the defense:

1) His complete audio recordings of his interviews with defendant Holmes and defendant Balwani;

2) His notes of any interviews of Holmes and Balwani; and

3) Documents given to Mr. Parloff by Theranos in connection with the *Fortune* Magazine feature article about the company.

These interview materials are complete and not abridged.

b) ***Objections Under Federal Rule of Criminal Procedure 17:***

The materials sought in Requests 1-12 (and any testimony sought in connection with them) are not evidentiary or relevant under the test in *United States v. Nixon,* 418 U.S. 683, 698 (1974): 1) They have no apparent, demonstrable or particularized relevance; 2) They are not demonstrably admissible (third party out of court statements by any interviewees would be patent hearsay in all events); 3) Statements from the listed third parties can be procured directly from the listed individuals themselves without having to break a Reporter's Privilege (many of them are on the witness list and subject to Defendant's reach); and 4) The Subpoena is an attempt to "sift" through the journalist's files to see *if* there *might* be

something that *might* prove useful, or *might* add color or cumulative value. In short, the Subpoena is a "fishing expedition" that imposes needless burden and cost on a third party.

c) ***Undue Harm and Interference***: Production of the records sought would unduly hamper *Fortune* and Mr. Parloff's ability to function in their independent journalistic roles. Among other things, were journalists drawn into legal disputes as a result of reporting on the wide range of topics they cover, a substantial burden would be imposed on them that would hamper their ability to independently and neutrally cover important and controversial issues of importance to the public and to effectively and credibly carry out its proper editorial function. Here Mr. Parloff provided limited and discrete documents to the litigants regarding Defendant's and Mr. Balwani's own statements to him.

d) ***Production Unduly Burdensome***: The production of the records sought is unduly burdensome because providing such information to all third party litigants on any issue covered by Mr. Parloff in the course of his journalistic activities would so overburden him and *Fortune* that it would be prevented from effectively carrying out its primary function as a news publication.

e) ***Subpoena Calls for Documents that Are Irrelevant and Not Necessary or Essential to the Captioned Litigation***: The Subpoena calls for information that is not essential to the subject litigation; and not evidence specifically relevant to the claims or defenses therein.

f) ***Information Is Otherwise Available. Other Avenues Must First Be Exhausted***: The information sought is available by other means without burdening Mr. Parloff. Defendant should first, and must first, exhaust other avenues of discovery before seeking these documents and/or testimony from journalists. If Defendant wishes to subpoena the persons whom she has named in the Subpoena to Mr. Parloff, she is well positioned to do

so. Most of them appear to be on the Witness List in the present case and their non-hearsay statements may be taken directly from them.

g) ***Overbroad and Lacking in Reasonable Particularity or any Particularized Need***: The requests as framed are overbroad and lacking in fair or reasonable particularity or specificity. To overcome a Reporter's Privilege, requests must be specific and the issuing party must be able to articulate a "particularized need" for the material sought – not just a generalized need or a speculative need.

h) ***Objection to Logging the Privilege***: The Reporter's Privilege would be violated by any requirement that each communication with sources and editors, etc. be identified, along with its date and its subject matter. It is precisely that information that is protected by the privilege. To provide such a list would permit an inquiring party to "sift" through a journalist's files to see if there might be something that might possibly be of interest to them. Such a requirement would defeat the privilege itself. All materials requested are, by their own terms, materials developed in the course of newsgathering and reporting which is the foundation for the assertion of the privilege. In this case, all document requests (1 through 12) by their own description constitute demands for protected newsgathering materials. Substantial portions of these materials were obtained by Mr. Parloff from various sources in confidence and are therefore due to an even higher level of protection. Hence, the demands *themselves* establish the foundation for the assertion of the Reporter's Privilege. They seek nothing more and nothing less than what is by definition covered by the Reporter's Privilege. In all events, a log would entail the disclosure of information about sources and reporting that the Privilege is precisely designed to protect. The demands are also so expansive, overreaching and lacking in reasonable specificity that no log could reasonably be prepared to address them. The Reporter's Privilege should and

does protect a journalist from specifying not only who is a source, but also who is *not* a source.

i) After Mr. Parloff learned that he had been misled and was contacted by the AUSA, he disclosed to the AUSA certain limited and specific documents. All of those materials that have been furnished to the AUSA have been provided to Defendant's counsel by the AUSA. Hence, there are no further disclosures required of Mr. Parloff.

j) ***Attorney-Client Privilege***: The Subpoena is so broad that it appears to call for documents that might be covered by the attorney-client or other applicable privilege. Given the overreaching and expansive nature of the requests and given that we are not yet able to assess whether attorneys were consulted in connection with any of the documents sought, we do not waive the attorney-client privilege for Mr. Parloff and we assert it here to preserve it. It is possible that attorneys were consulted in connection with some of the documents or articles sought, but Defendant should first identify with particularity the documents to which she believes she is actually entitled before any attorney-client privilege is assessed and before it can be effectively asserted with particularity.

Dated: September 15, 2021

MILLER KORZENIK SOMMERS RAYMAN LLP

By: _____

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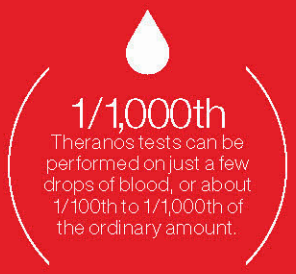
EXHIBIT C



New Blood

ELIZABETH HOLMES FOUNDED HER REVOLUTIONARY BLOOD DIAGNOSTICS COMPANY, THERANOS, WHEN SHE WAS 19. IT'S NOW WORTH MORE THAN $9 BILLION, AND POISED TO CHANGE HEALTH CARE.

by Roger Parloff

IN THE FALL OF 2003, Elizabeth Holmes, a 19-year-old sophomore at Stanford, plopped herself down in the office of her chemical engineering professor, Channing Robertson, and said, "Let's start a company." ¶ Robertson, who had seen thousands of undergraduates over his 33-year teaching career, had known Holmes just more than a year. "I knew she was different," Robertson told me in an interview. "The novelty of how she would view a complex technical problem—it was unique in my experience."

PHOTOGRAPH BY JOE PUGLIESE

Founder and CEO Holmes undergoing the blood test she invented at a public clinic at Theranos's headquarters in Palo Alto

Holmes had then just spent the summer working in a lab at the Genome Institute in Singapore, a post she had been able to fill thanks to having learned Mandarin in her spare hours as a Houston teenager. Upon returning to Palo Alto, she showed Robertson a patent application she had just written. As a freshman, Holmes had taken Robertson's seminar on advanced drug-delivery devices—things like patches, pills, and even a contact-lens-like film that secreted glaucoma medication—but now she had invented one the likes of which Robertson had never conceived. It was a wearable patch that, in addition to administering a drug, would monitor variables in the patient's blood to see if the therapy was having the desired effect, and adjust the dosage accordingly.

"I remember her saying, 'And we could put a cellphone chip on it, and it could telemeter out to the doctor or the patient what was going on,'" Robertson recounts. "And I kind of kicked myself. I'd consulted in this area for 30 years, but I'd never said, here we make all these gizmos that measure, and all these systems that deliver, but I never brought the two together."

Still, he balked at seeing her start a company before finishing her degree. "I said, 'Why do you want to do this?' And she said, 'Because systems like this could completely revolutionize how effective health care is delivered. And this is what I want to do. I don't want to make an incremental change in some technology in my life. I want to create a whole new technology, and one that is aimed at helping humanity at all levels regardless of geography or ethnicity or age or gender.'"

That clinched it for him. "When I finally connected with what Elizabeth fundamentally is," he says, "I realized that I could have just as well been looking into the eyes of a Steve Jobs or a Bill Gates."

With Robertson's blessing, Holmes started her company and, a semester later, dropped out to pursue it full-time. Now she's 30, and her private, Palo Alto–based corporation, called Theranos—the name is an amalgam of the words "therapy" and "diagnosis"—has 500 employees and has raised more than $400 million from equity sales to investors who have effectively valued the company at more than $9 billion. All these numbers, confirmed to me by an outside director, are being published here for the first time. Though Theranos is largely unknown even in Silicon Valley, that is about to change.

"This is about being able to do good," Holmes says to me about her company. "And it's about being able to change the health care system through what we believe this country does so well, which is innovation and creativity and the ability to conceive of technology that can help solve policy challenges."

At first glance it's hard to see the connection between the patch that wowed Robertson and what Theranos does now. But as we will see, to Holmes they are simply different "embodiments" of the same core insights.

Theranos today is a potentially highly disruptive upstart in America's $73 billion diagnostic-lab industry, which performs nearly 10 billion tests a year and is estimated to provide the basis for about 70% of doctors' medical decisions. Medicare and Medicaid each pay roughly $10 billion annually on reimbursements for these tests.

Theranos runs what's called a high-complexity laboratory, certified by the federal Centers for Medicare & Medicaid Services (CMS), and it is licensed to operate in nearly every state. It currently offers more than 200—and is ramping up to offer more than 1,000—of the most commonly ordered blood diagnostic tests, all without the need for a syringe.

Theranos's tests can be performed on just a few drops of blood, or about 1/100th to 1/1,000th of the amount that would ordinarily be required—an extraordinary potential boon to frequently tested hospital patients or cancer victims, the elderly, infants, children, the obese, those on anticoagulants, or simply anyone with an aversion to blood draws. Theranos phlebotomists—technicians licensed to take blood—draw it with a finger stick using a patented method that minimizes even the minor discomfort involved with that procedure. (To me, it felt more like a tap than a puncture.)

The company has performed as many as 70 different tests from a single draw of 25 to 50 microliters collected in a tiny vial the size of an electric fuse, which Holmes has dubbed a "nanotainer." Such a volley of tests with conventional techniques would require numerous tubes of blood, each containing 3,000- to 5,000-microliter samples.

The fact that Theranos's technology uses such microscopic amounts of blood should eventually allow physicians far greater latitude when ordering so-called reflex tests than they have previously enjoyed. With reflex testing, the physician specifies that if a certain test comes up abnormal, the lab should immediately perform follow-up tests on the same sample to pinpoint the cause of the abnormality. Reflex testing saves patients the time, inconvenience, cost, and pain of return doctor visits and additional blood draws.

The results of Theranos's tests are available within hours—often matching the speed of emergency "stat" labs today, though stat labs, which are highly inefficient, can usually perform only a limited menu of maybe 40 tests.

Most important, Theranos tests cost less. Its prices are often a half to a quarter of what independent labs charge, and a quarter to a 10th of what hospital labs bill, with still greater savings for expensive procedures. Such pricing represents a potential godsend for the uninsured, the insured with high deductibles, insurers, and taxpayers. The company's prices are set to never exceed half the Medicare reimbursement rate for each procedure, a fact that, with widespread adoption, could save the nation billions. The company also posts its prices online, a seemingly obvious service to consumers, but one

PREVIOUS PAGE: GROOMING BY TAMARA BROWN—ARTIST UNITED

PHOTOGRAPH BY DREW KELLY

Theranos can run as many as 70 tests on a sample this size, obtained by pricking a finger.

"THIS IS THE TRUE TRANSFORMATION OF HEALTH CARE, RIGHT HERE IN FRONT OF US."

—Mark Laret, CEO, UCSF Medical Center

that is revolutionary in the notoriously opaque, arbitrary, and disingenuous world of contemporary health care pricing.

PRECISELY HOW THERANOS accomplishes all these amazing feats is a trade secret. Holmes will only say—and this is more than she has ever said before—that her company uses "the same fundamental chemical methods" as existing labs do. Its advances relate to "optimizing the chemistry" and "leveraging software" to permit those conventional methods to work with tiny sample volumes.

The scale of Theranos's operations at the moment is modest. Its phlebotomists currently take physician-ordered blood draws (and saliva, urine, feces, and other samples) at collection centers the company operates at its headquarters in Palo Alto and at 21 Walgreens—one in Palo Alto and the rest in Phoenix. But these are only the advance guard in a gradual national rollout that Walgreens committed to last September; it plans to establish Theranos outposts in a substantial percentage of its 8,200 drugstores in all 50 states. It is the first step in Holmes's audacious plan to place a Theranos center within five miles of almost every American and within one mile of every city dweller. Walgreens CEO Greg Wasson told me in an interview that he hopes to eventually put them in the pharmacies of the company's European partner chain, Alliance Boots, as well.

At least as significant, three hospital groups are now working closely with Theranos with the aim of deploying its lab services—UCSF Medical Center in San Francisco, Dignity Health's 17-state hospital group, and Intermountain Healthcare's 22-hospital system in Utah and Idaho.

"I just think this is so exciting," says Mark Laret, the CEO of UCSF Medical Center, about what he's seen so far. "I mean, here it is. This is the true transformation of health care, right here in front of us."

"The first time I heard about this, I thought it was snake

A Singular Board

WITH THREE FORMER CABINET SECRETARIES, TWO FORMER SENATORS, AND RETIRED MILITARY BRASS, IT'S A BOARD LIKE NO OTHER.

THOUGH LITTLE KNOWN and privately held, Theranos has assembled what may be, in terms of public service, the most illustrious board in U.S. corporate history. It includes three former U.S. cabinet secretaries, two former U.S. senators, a retired Navy admiral and a retired Marine Corps general.

In 2011, explains company founder Elizabeth Holmes, she realized that changing the way health care is delivered in this country would require the help of great strategists.

That July she finagled an introduction to George Shultz (above), the former Secretary of State, Treasury, and Labor, at Stanford's Hoover Institution. Shultz had held four cabinet-level positions, counting his stint as director of the Office of Management and Budget, and had also been president of engineering giant Bechtel Group and a director at biopharmaceutical company Gilead Sciences.

Their scheduled 10-minute interview lasted 2½ hours. Shultz was captivated by what Holmes's technologies could mean for health care, but was struck also by her "purity of motivation," he says. He joined Theranos's board that same month.

"He and I have seen each other at least once a week since I first met him," Holmes says.

Three years later nearly all the other outside directors on Theranos's board are people who were introduced to the company through Shultz, now 93. They are former Secretary of Defense Bill Perry, former Secretary of State and National Security Adviser Henry Kissinger, former U.S. Senators Sam Nunn and Bill Frist (a heart-transplant surgeon), retired U.S. Navy Adm. Gary Roughead, retired U.S. Marine Corp Gen. James Mattis, former Wells Fargo CEO and chairman Dick Kovacevich, and former Bechtel Group CEO Riley Bechtel.

"My belief is," says Shultz, "that if you're making a contribution, you're living. If you're not making any kind of contribution, well—. That's my motivation, and it's very parallel to Elizabeth's."

oil and mirrors," says David Helfet, the chief of orthopedic trauma at the Hospital for Special Surgery in Manhattan. But after reviewing voluminous validation studies supplied to him by the company, he has become a believer and is urging his hospital to consider adoption.

"It's real data," he says. "It's not their interpretation." (Theranos has invited Helfet to join its medical advisory board, he says, but he has not yet decided whether to do so.)

Helfet sees an opportunity to enlist Theranos lab services in the identification of so-called hospital-acquired infections—a major scourge in health care today. Conventional methods of identifying germs and figuring out which antibiotics will combat them—growing bacteria on agar in petri dishes—can require three to five days, during which patients languish in hospital beds, take ineffective antibiotics, and incubate antibiotic-resistant bacteria. Using DNA profiling Theranos can, for less than the cost of the conventional tests, identify a bug and its resistance profile within four hours, says Helfet, according to the data he has seen.

"That would be huge," he says. "That would change the way we practice medicine." (Though Theranos did not invent DNA testing of this kind, Holmes says, it has found ways to make it cost-efficient.)

Importantly, it's not just the blood draws that are tiny. It's also the analytical systems Theranos uses to perform the tests. They take up a small fraction of the footprint required by a conventional lab today.

"It takes at least 10 times—and maybe 100 times—less space for doing the same thing," says Laret of UCSF Medical Center. That makes it possible to imagine one day placing Holmes's labs right by the operating rooms in hospitals or in military evacuation helicopters or on ships and submarines or in refugee camps or in tents in the African bush. (The analyzers look like large desktop computer towers. Holmes declines to explain how they work, or even allow them to be photographed, citing the need to protect trade secrets. The company manufactures them at an unmarked facility I toured in a research park across the South Bay from Palo Alto, in Newark, Calif.)

What do incumbent players in the blood-diagnostic space think about all of this? The most frequent criticism is that Theranos is using purportedly breakthrough technology to perform tests that are relied on for life-and-death decisions without having first published any validation studies in peer-review journals. "I don't know what they're measuring, how they're measuring it, and why they think they're measuring it," says Richard Bender, an oncologist who is also a medical affairs consultant for Quest Diagnostics, the largest independent diagnostic lab.

Holmes counters that because, as noted, her tests employ "the same fundamental chemical methods" as existing tests,

ERIC THAYER—GETTY IMAGES

peer-review publication of validation studies is both unnecessary and inappropriate.

The backdrop for this dispute is an unusual regulatory structure that does, in fact, confer upon some—though not all—conventional lab tests an extra layer of validation that Theranos's do not yet have. Most labs, like Quest and Laboratory Corp. of America, perform many of their routine tests using analyzers they buy from medical-device manufacturers, like Siemens, Olympus, and Beckman Coulter. Before those manufacturers can sell such equipment, they must obtain U.S. Food and Drug Administration approval for the tests those analyzers perform—a process that is in addition to, and more searching than, the audits and proficiency tests required to win CMS certification for the lab itself.

At the same time, for other procedures conventional labs will devise their own lab-developed tests, or LDTs, which they do not have cleared by the FDA. While the FDA takes the position that it could require approval for LDTs, for many years it has said it would forgo that right in the exercise of its "enforcement discretion."

Theranos, which does not buy any analyzers from third parties, is therefore in a unique position. While it would need FDA approval to sell its own analyzers to other labs, it doesn't do that. It uses its analyzers only in its own CMS-certified lab. All its tests are therefore LDTs, effectively exempt from FDA oversight.

Holmes sees no basis for criticizing Theranos for acting within this framework, since no other labs seek FDA approval of their own LDTs. "Existing labs use thousands of assays that are neither FDA approved nor peer reviewed," she says, referring to their LDTs. (In fact, the American Clinical Laboratory Association, the trade group for traditional diagnostic labs, adamantly opposes any effort by the FDA to start requiring approval of LDTs and even takes the position that the FDA lacks legal authority to do so.)

Moreover, Holmes stresses, Theranos is currently seeking FDA clearance for every one of its tests, even though it's under no legal obligation to do so. (She has submitted many hundreds of pages of validation data in this effort, and has shown much of that data to *Fortune*.) Theranos may, in fact, be the only lab to have ever sought FDA clearance for LDTs.

Beyond the validation disputes, skeptics also question Theranos's business model. They doubt its ability to scale up anytime soon to the levels necessary to become a serious competitor, especially since the business has so many unglamorous aspects unrelated to testing—billing, customer service, sorting, regulatory compliance, and the logistics of transporting samples from physicians to labs. Quest, for instance, employs 45,000 people; owns a fleet of 3,000 vehicles and 20 airplanes; and runs eight regional hub labs, 150 satellite labs, and 2,200 patient service centers.

DREW KELLY

The Theranos "wellness center" at the Walgreens drugstore in downtown Palo Alto. Theranos's prices for tests are often a half to a quarter of independent lab prices and a quarter to a 10th of hospital lab prices.

Critics are likewise puzzled by the cosmic vastness of Holmes's end-to-end business model. If Theranos is making breakthrough analyzers, they wonder, why doesn't it just sell them to existing labs? To these critics, for Theranos to compete in the lab business itself while making all its own analyzers sounds implausible, if not crazy—like FedEx trying to manufacture all its own airplanes and trucks.

Still, Holmes has convinced a lot of people that she's onto something. She has assembled what, in terms of public service at least, may be the single most accomplished board in U.S. corporate history (see box). It includes former U.S. Secretary of State, Treasury, and Labor George Shultz; former Secretary of Defense Bill Perry; former Secretary of State and National Security Adviser Henry Kissinger; and former U.S. Senators Sam Nunn and Bill Frist (who is also a heart transplant surgeon), among others.

As a bonus, board meetings are also attended by the company's de facto legal adviser at large, trial lawyer David Boies. At 73, Boies may be the most eminent living trial lawyer, when one tallies up such cases as his civil antitrust prosecution of Microsoft from 1998 to 2000, his role in the historic *Bush* v. *Gore* matter of 2000, and his fight to legalize same-sex marriage.

Because of his admiration for Holmes and what her company is trying to do, Boies says, he agreed to represent Theranos personally in its first challenge from patent holders claiming infringement—something of a coming-of-age ritual for tech startups. In a rare if not unprecedented rout this

past March, the patent holders unconditionally surrendered midtrial, stipulating to the invalidity of their own patent. As a kicker they agreed—though the presiding judge would have been powerless to order such a thing himself—to bring no additional patent suits against Theranos for five years.

Though Holmes faces enormous challenges, she seems to consistently attract the service of extraordinary people and to inspire extraordinary fealty in them.

"She really does want to make a dent in the universe—one that is positive," says retired U.S. Marine Corps Gen. James Mattis, explaining why he signed up last fall as another of Theranos's strikingly illustrious outside directors. Mattis had stepped down just months earlier as commander of the U.S. Central Command—the chief of U.S. military operations in the Middle East and Central Asia, including Afghanistan—a post he had taken over from David Petraeus in 2010.

"The strength of the leader's vision in the military is seen as the critical element in that unit's performance," Mattis says. "I wanted to be around something again that had that sort of leadership."

IN A CONFERENCE ROOM at her 140,000-square-foot, open-floor-plan headquarters at the Stanford Research Park—a former home to Facebook and, before that, to the iconic Palo Alto tech firm Hewlett-Packard—Holmes grips a plastic cup of unappetizing green juice. Her first of the day, it is made from spinach, parsley, wheatgrass, and celery. Later she'll switch to cucumber. A vegan, she long ago dropped coffee in favor of these juices, which, she finds, are better able to propel her through her 16-hour days and seven-day weeks.

She admits—laughing nervously at the eccentricity of it—that after a meal she sometimes examines a drop of her own or others' blood on a slide, and says she can observe the difference between when someone has eaten something healthy, like broccoli, and when he's splurged on a cheeseburger. When we dine one night at an Italian place downtown with $14 pastas, the manager knows what she'll have: a spartan, dressingless mixed salad and an oil-free spaghetti with tomatoes, prepared from whole-wheat noodles she has provided the restaurant in advance, since it doesn't stock them. No wine.

During my four days at Theranos, Holmes dressed identically every day: black jacket; black mock turtleneck; black slacks with a wide, pale pinstripe; and black low-heel shoes. Steve Jobs, because of his vision and perfectionism about "great products"—words Holmes punches out with precisely Jobs' brio—is obviously a hero to her. As an apparent memento mori, she hangs in her office a framed screenshot of his Apple Internet bio, printed out on Aug. 24, 2011, the day he stepped down as CEO because of pancreatic cancer.

From still photos of Holmes herself—young, blond, and blue-eyed—cynics might be excused for thinking, "Oh, I get it. I see why all these geezers are gushing about her company."

And from small talk with her, one might still wonder what all the fuss was about. She is polite and soft-spoken. She listens. She laughs naturally at other people's jokes and doesn't try to trump them. Her voice is lower pitched than you might expect, but that's about all you notice at first. That, and her youth.

"She looks like 19," says board member Henry Kissinger, 91.

Asked to assess her as a leader—because he's seen a few—he responds, "I can't compare her to anyone else because I haven't seen anyone with her special attributes. She has iron will, strong determination. But nothing dramatic. There is no performance associated with her. I have seen no sign that financial gain is of any interest to her. She's like a monk. She isn't flashy. She wouldn't walk into a room and take it over. But she would once the subject gets to her field."

And she does, when she begins explaining to me the "mission."

"Consumerizing this health care experience is a huge element of our mission," Holmes says at our first meeting in April, "which is access to actionable information at the time it matters." In our conversations over the next two months, she comes back to that phrase frequently. It is the theme that unifies what had seemed to me, at first, a succession of diverse, disparate aspects of her vision.

"There's a lot of ways we've focused on access," she explains, including the use of the minimally invasive finger stick, the affordability, the convenience of a drugstore location. The Walgreens "wellness centers," as they are called, are open evenings and weekends so that people won't have to miss work to get their blood test done. Each center is, within its Walgreens, an oasis, playing calming music—vaguely Eastern recorder melodies when I was there—and displaying nature scenes over a high-def LCD monitor (an aquarium video, in my case). The phlebotomist envelops the patient's finger in a cozy, warming wrap, massages it with a soothing, milking motion, then pulls the trigger on an unusually shallow, narrow-gauge lancet.

"Anywhere from 40% to 60% of people, when they're given a requisition by a doctor to go get tested, don't," asserts Holmes, "because they're scared of needles or the locations are inconvenient or the cost is too high. And if you're not even getting tested, how is it possible that we're going to move toward an era of preventive medicine?"

Preventive medicine—and this relates to the "at the time it matters" portion of her mission statement—is crucial to the mission. She is making diagnostic testing so accessible in all these different ways precisely so that people can eventually do it more often, almost the way they might use a bathroom scale to watch their weight.

Today people might have their blood tested once a year,

she explains. They get a snapshot of certain key values and learn whether they are "in range"—that is, statistically normal—or "out of range." But if they were tested more often, they would begin to see a "movie" of what's going on inside them. Sudden, rapid changes in some protein concentration—even when technically still in range—could tip off the doctor that something was amiss, and do so before it was too late to address the problem. (Theranos plans soon to display results in a way that maps them against all previous results from tests it has performed for that patient.)

"The movie goal is absolutely core to what we're working to do," she says. "When you have that trend, it is a much more meaningful clinical data set for the physician to use."

She knows that, she says, "because we've seen it." She's referring to the fact that since 2005 Theranos has been doing work for major pharmaceutical companies, including Pfizer and GlaxoSmithKline, that are conducting clinical drug trials. Early on it was a way for the company, working under confidentiality agreements, to stealthily refine its technology while earning revenue needed to build out infrastructure. Theranos would test drug-trial subjects three times a week—which wouldn't have been feasible using venipuncture—and catch adverse drug effects quickly, before they became dangerous.

"We're building an early-detection system," she explains. "I genuinely don't believe anything else matters more than when you love someone so much and you have to say goodbye too soon. I deeply believe it has to be a basic human right for everybody to have access to the kind of testing infrastructure that can tell you about these conditions in time for you to do something about it. So that's what we're building."

HOLMES WAS BORN in February 1984 in Washington, D.C. Her father, Christian Holmes IV, has devoted most of his life to public-minded government service—disaster relief in Africa, international development projects in China, environmental work in this country—and is currently the global water coordinator for the U.S. Agency for International Development. He met Elizabeth's mother, Noel, on Capitol Hill, where she worked as a congressional committee staffer.

When she was young, Elizabeth read a biography of her great-great-grandfather, the first Christian Holmes, who was a decorated World War I veteran, engineer, inventor, and surgeon after whom a hospital at the University of Cincinnati Medical Center is named. When she was 8, her family took a trip there to see a display about him.

"He ultimately worked himself to death," Elizabeth tells me—he died at 62—"but he was so passionate in what he did. I wondered, Would I want to be a doctor?"

But she soon discovered she couldn't handle the sight of blood, even fainting when friends arranged an opportunity for her to watch some surgeries performed. Though her parents remember Elizabeth as a fearless child, the lone exceptions, they say, were getting shots and enduring blood draws.

"The concept of sticking a needle into you and sucking your blood out," Holmes says, has always been profoundly disturbing to her. As a child, she says, "when I knew I needed to get a test, I would really be focused on that for weeks in advance." As an adult, she refused to get them. In fact, the last time she endured a venipuncture was in 2007, she says, when her board demanded that she get key-man insurance.

When Elizabeth turned 9, her father took a private sector job with the industrial conglomerate Tenneco. He went to Houston to find a house for the family to move into. He remembers feeling guilty about forcing Elizabeth and her younger brother, Christian Holmes V, to uproot themselves from their happy lives in D.C. So he was profoundly touched when he got a letter from Elizabeth reassuring him that "I love adventures," that she was looking forward to having "new ones in Texas," especially since Texas was "big on science." But the most striking thing about his 9-year-old's "Dear Daddy" letter was its first sentence: "What I really want out of life is to discover something new, something mankind didn't know was possible to do," she wrote.

Elizabeth and her brother—who is now director of product management at Theranos—had both been intrigued by their father's work in China. So when Elizabeth was about 9, her parents found them both a tutor to teach them Mandarin on Saturdays. Elizabeth then supplemented those lessons with summer language programs at Stanford and, later, at two universities in Beijing. Captivated by computer programming in high school, she was struck by how the Chinese universities' information technology facilities lagged behind what she was used to. To rectify that situation, she started her first business while still in high school, selling C++ compilers to Chinese universities.

Whether it grew out of her father's experiences at Tenneco or family lore—they are descendants of a founder of the Fleischmann's Yeast company—Elizabeth grew up admiring private industry. "At a relatively early age I began to believe that building a business was perhaps the greatest opportunity for making an impact," she says, "because it's a tool for making a change in the world."

Holmes was admitted by early decision to Stanford. As she headed off to college, her father gave her a copy of *Meditations*, by the Roman emperor and Stoic philosopher Marcus Aurelius. "I wanted it to reinforce the message of a purposeful life," her father explained to me. "I think it really affected her."

Upon admission, Holmes was named one of an elite group of freshmen denominated "president's scholars," which meant that Stanford would spot them $3,000 each to use on a research project. While still a freshman, Holmes persuaded her chemical engineering professor, Robertson, to let her use

the stipend for a research project in his lab, though it would mean working mainly alongside Ph.D. candidates.

That summer she departed for Singapore to work in the lab at the Genome Institute, which was developing novel systems to detect the SARS virus in blood or nasal swabs. "I had not had much formal biology training," Holmes recalls, so she had to bring herself up to speed in that respect on her own. At the same time, her engineering and technology background at Stanford led her to believe that "there were much better ways to do" the tests she saw being performed at the institute.

As soon as she got back to the U.S., Holmes started writing a patent application embodying the ideas set in motion by that experience. "I saw her sit down at the computer, and for five to six days she barely got up," recalls her mother, Noel. "I would bring her food occasionally, and she slept maybe one or two hours a night for five nights."

The day after Elizabeth finished the draft, Noel started driving her from Houston to Stanford, hoping to enjoy some mother-daughter quality time. But Elizabeth just slept for two days in the car.

Noel and Chris knew then that Elizabeth wanted to start a business, though they didn't understand the details. It therefore came as no shock the following semester when she told them she needed to suspend college to pursue the company full-time. They let her take the money they'd saved for her education and put it into her business.

"What do you want for your children?" says Noel. "You want them to do something they're passionate about. To follow their dream. To help people. To change the world. So we said, 'Of course. Go do this.'"

IN WHAT RESPECT, then, does Holmes's first patent application—the wearable patch that would radio the doctor what is going on in your blood in real time—lead to Theranos, a player in the $73 billion diagnostic lab business?

When one returns to her core mission—making actionable information accessible at the time it matters—one glimpses part of what she means. The patch permitted physicians and patients to see the "movie" of what was going on inside patients' blood. The original name for her company was Real-Time Cures, though she soon scratched that, after deciding that too many people had a "cynical" reaction to the word "cure."

"Elizabeth has had a very clear vision of where she wanted to take this since the time I met her," says Sunny Balwani, who met her in 2002 and has been Theranos's president since 2009. "The business strategy, the tactics of what to do first, what to offer when—that has changed, but the overall goal and direction has been linear." Balwani, who founded and sold his own e-commerce company in the 1990s, is an expert in building software products.

For 10 years Holmes patiently raised money and refined her technologies. As much as she needed money, she turned down many offers, she says, because so many investors wanted quick returns.

"Too often the question is, What's your exit strategy?" she recounts, "before you're really understanding what your entry strategy is." She is building a company, she explains, that "30, 40, even 50 years from now will be defining new standards in terms of the way in which people will be able to get access to actionable information."

Early investors included venture capitalists Draper Fisher Jurvetson (which has funded Tesla and SpaceX), ATA Ventures, Silicon Valley legend Don Lucas Sr. (Oracle, National Semiconductor, Macromedia), and Oracle's Larry Ellison. She will not identify later investors other than to say they include private equity funds and "strategic partners," by which she means "entities working with the company as we scale." Though she has now raised more than $400 million, she says she has retained control over more than 50% of the stock.

All the while, Holmes has continued to invent and to upgrade her earlier inventions. "As she likes to put it," says board member Shultz, "the best patent is making yourself obsolete. So the person who steals your patent steals yesterday's technology."

Today Holmes is a co-inventor on 82 U.S. and 189 foreign patent applications, of which 18 in the U.S. and 66 abroad have been granted. Those are in addition to another 186 applications Theranos has filed worldwide that don't list Holmes as an inventor, of which 18 have already been granted.

ALTHOUGH I BELIEVE Balwani when he says that Holmes's "overall goal and direction" for the company "has been linear," I don't believe that Walgreens wellness centers represent the ultimate target of that vector. There are pieces of the puzzle we haven't seen yet. In some cases she may be waiting for regulatory approval, while in others she may just be waiting, like Steve Jobs, to finish perfecting her next "great product" before unveiling it with a flourish.

As Holmes relentlessly pursues the next "embodiment" of her vision, her old chemical engineering professor, Robertson, sits about 20 yards from her office, helping her. After years of volunteer service to the company as a director, he became a paid consultant in 2009. Last June he signed up as an employee.

"I gave up two endowed chairs to do this," he says. "I think that's a statement."

Then he adds, "To me, I wish I wasn't 70 years old. I wish I was her age and could be in on this. Because this is going to be a long, exciting, fascinating, exhilarating ride."

FEEDBACK *roger_parloff@fortune.com*

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EXHIBIT E

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How Theranos Misled Me

photo-color:

In a June 2014 cover story for Fortune, I helped raise to prominence the inventor-entrepreneur Elizabeth Holmes and her remarkable—I think everyone will still go along with that adjective—diagnostics company Theranos.

Fairly high up in my story there is a whopping false statement. After explaining that Theranos's tests could be performed with a finger-stick, rather than using traditional venipuncture (a syringe in the crook of the arm), I wrote that the company "currently offers 200—and is ramping up to offer more than 1000—of the most commonly ordered blood diagnostic tests, all without the need of a syringe."

Sixteen months later, John Carreyrou of the *Wall Street Journal* published a now famous front-page story containing a wide range of unflattering accusations about Theranos. Among them, he reported that one "former senior employee" had told him—in an account generally corroborated by three other former employees—that as of December 2014, the company was actually performing only about 15 finger-stick tests using its proprietary technology; the remainder were being performed using conventional, third-party analyzer machines, made by companies like Siemens—i.e., the same machines used by conventional labs like Quest Diagnostics DGX and LabCorp LH.

In that *Journal* article, a Theranos spokesperson was quoted flatly denying the newspaper's allegations in a blanket manner, but refusing to be specific, citing trade secrets. Notably, from my perspective, she did not say how many tests the company had, in fact, been performing by proprietary methods in December 2014.

In a longer statement issued the same day on its website, Theranos further blasted the *Journal* for, among other things, relying on the accounts of "anonymous, disgruntled former employees," but still declined to state how many proprietary tests it had really been performing.

It wasn't until a week later—on Oct. 22—that Theranos, after stonewalling and threats of legal action failed to quell the furor, offered a serious, 14-page response to the *Journal* article, addressing the full panoply of its accusations. Among other things the company asserted that, as of December 2014, it had in fact been performing "more than 80 of the tests on our online test menu via finger-stick," and that all but "a few" of those "ran using proprietary technologies." It also asserted that in the fourth quarter of 2014, 57% of all tests ordered had been performed by finger-stick.

Those figures, if accurate, would suggest that the company might well be accomplishing, as it has claimed, something genuinely innovative and beneficial to society. I should add that the company's extremely low prices and price-transparency would also be of unquestionable benefit to society, even if the company weren't doing *anything* technologically innovative. On the other hand, all these advances matter only if Theranos's tests are also reliable, which the *Journal* article also cast doubt upon. In my opinion, the evidence for this was weaker than its evidence that the company was misrepresenting its accomplishments.

After Theranos's Oct. 22 statement, I contacted officials there to inquire how many tests it had actually been commercially performing by proprietary means in June 2014, when I had reported that it was offering more than 200. A spokesperson acknowledged to me that it was fewer than 200, but declined to specify how many. She said she'd send a statement.

(*Editor's note:* In the meantime, Holmes gave the following interview with *Fortune* Editor Alan Murray at the Fortune Global Forum:)

[VIDEO]

The company's statement arrived Nov. 3. "As discussed when you visited Theranos," it said, "Theranos could perform hundreds of tests (more than 200) using its proprietary technologies. The reports you reviewed at Theranos covered many of those tests Theranos developed for use with finger-stick samples."

(The company had, indeed, provided me in the Spring of 2014 with what it said were—and what looked to be—validation studies for scores of different diagnostic tests, though, in truth, I lacked the expertise to assess their significance.)

The statement then went on to address my followup question, which was basically: *If you were capable of doing 200-plus tests using your proprietary methods, why weren't you in fact doing them?*

Here, with trademark, Theranos-ian opacity, is the reply:

Over time, we've been optimizing our clinical lab to bring up tests that are more commonly ordered, and in some cases move resources off the proprietary tests that are less commonly ordered to get to a point where the ordering patterns we are seeing can all be accommodated through our finger-stick technology.

Got that?

I then started looking back at my research for the original story—which had been conducted, by then, 17-19 months earlier—to try to reconstruct how I made the error.

As much as I'd like to say that Holmes lied to me, I don't think she did. I do believe I was misled—intentionally—but I was also culpable, in that I failed to probe certain exasperatingly opaque answers that I repeatedly received.

"We do routine, specialty, and esoteric tests," Holmes told me in May 2014. "What we've done is take those, and develop the chemistry and analytic systems that made it possible to run them on a microsystem."

When I started my research in March 2014, there were maybe something like 100 tests listed on Theranos's online test menu. The number was gradually climbing as my work continued. By the time I was ready to publish there were 214 tests listed. I assumed that meant they had now adapted 214 tests to run on their microsystem.

In fact, at the time I didn't know what else it could have meant. That's because, so far as I can tell, at the time of my research the company had never revealed that it ever used conventional, nonproprietary analyzers to perform the tests it listed on its menu other than for research purposes.

About a year later—in May *2015*—Holmes did explain to me, as I reported then, that the company had begun using such third-party analyzers, analyzing blood drawn by venipuncture. It had begun doing so, she explained, in order to be able to perform less commonly ordered tests, which she referred to as "esoteric" tests, thereby providing customers with one-stop shopping. This was presented to me as a new development, however—a departure from prior practice.

In mid-September 2015—after an inspection at which an FDA official opined that the company's tiny blood collection device, known as a nanotainer, was an "uncleared" medical device—Theranos discontinued using its proprietary methods for all but at most one test, for which it had already received full FDA approval. This fact didn't come to light until a month later, about a day after Carreyrou's first article, and just a few hours before his second.

Back in early 2014, on both its website and in press releases of that time, Theranos did disclose that "we can use a tiny finger-stick or collect a *micro-sample* from a venous draw" (emphasis added). It thereby acknowledging that it was capable of doing venipuncture, but stressed that even then it strived to take only *micro-samples*. In our conversations, Holmes defined the word "micro-sample" as referring to the "tiny samples" or "these tiny droplets we take."

Thus, "micro-samples"—whether from finger-stick or venipuncture—were what the company was about, and my assumption was that in either case they were being analyzed by the same proprietary devices, which were designed specifically to read tiny samples.

The company's, ads, promotional materials, and posters hanging on the headquarter walls, all seemed to hammer home this point. They featured slogans like "One tiny drop changes everything"; "All the same tests. One tiny sample"; and "1/1000th the size of a typical blood draw; Theranos runs any test available in central laboratories."

My interviews with Holmes in 2014 seemed to further reenforce the point. "When we do collect venipuncture," Holmes explained to me back then, "we take a smaller sample than traditionally required and we also use the smallest needle. It's a tiny butterfly needle. The least painful. So it is a smaller volume."

Surely this meant they were still analyzing these tiny draws with their proprietary devices—the ones uniquely designed to do so, I thought.

Nevertheless, the truth is that there was at least one great, flapping red flag that I missed. By May of 2014, I had already heard about anecdotes in which people had shown up at one of Theranos's Wellness Centers and had been disappointed to learn that the test they ordered would require a venipuncture draw.

So I asked why that sometimes happened.

"The biggest reason," Holmes told me in May 2014, "is we're scaling. As we're building out this infrastructure, we're also building out our inventory and our capacity in terms of the number of samples that we can handle at any given point in time.... We'll use venipuncture in addition to the micro-samples just to handle the volume of sample that we're processing."

I couldn't understand why venipuncture would help cope with volume. *Were they running out of nanotainers or some other specialized piece of equipment needed for fingerstick draws at some of the Wellness Centers? Running short of some reagent? Or was it just that they hadn't yet adapted certain tests for their proprietary platform?*

"It's more how we configure our own analytical systems," she said, "and the capacity that we have in those systems at any given point in time. And it evolves and it's changing. Every week we have more and more capacity."

I remember coming back to this point again later: *How exactly would venipuncture help them cope with volume?*

I was told that my question was getting into the realm of trade secret.

A secret, for sure. But maybe a different kind of secret.

So I blew it. And I should have included all these colloquies in the original story. I regret the error.

http://fortune.com/2015/12/17/how-theranos-misled-me-elizabeth-holmes/

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By Roger Parloff

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